



PTO/SB/08A (10-01)

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Substitution for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>			Complete if Known		
			Application Number	10/777,542	
			Filing Date	February 12, 2004	
			First Named Inventor	Unchalee Kositprapa	
			Art Unit		
			Examiner Name		
			Attorney Docket Number	141-446	
Sheet	1	of	5		

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. 1	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number- Kind Code* (If known)			
/KW/	AA	us- 3,174,901	03-23-1965	Sterne	
/KW/	AB	us- 3,960,949	06-01-1976	Ahrens et al.	
/KW/	AC	us- 4,166,800	09-04-1979	Fong	
/KW/	AD	us- 4,389,330	06-21-1983	Tice et al.	
/KW/	AE	us- 4,687,777	08-18-1987	Meguro et al.	
/KW/	AF	us- 4,839,177	06-13-1989	Colombo et al.	
/KW/	AG	us- 4,891,223	01-02-1990	Ambegaonkar et al.	
/KW/	AH	us- 4,968,507	11-06-1990	Zentner et al.	
/KW/	AI	us- 5,294,770	03-15-1994	Riddle et al.	
/KW/	AJ	us- 5,356,913	10-18-1994	Colca	
/KW/	AK	us- 5,376,771	12-27-1994	Roy	
/KW/	AL	us- 5,478,852	12-26-1995	Olefsky et al.	
/KW/	AM	us- 5,602,133	02-11-1997	Antonucci et al.	
/KW/	AN	us- 5,658,474	08-19-1997	Geerke	
/KW/	AO	us- 5,681,584	10-28-1997	Savastano et al.	
/KW/	AP	us- 5,698,220	12-16-1997	Cardinal et al.	
/KW/	AO	us- 5,719,188	02-17-1998	Colca	
/KW/	AR	us- 5,859,037	01-12-1999	Whitcomb	
/KW/	AS	us- 5,916,584	06-29-1999	O'Donoghue et al.	
/KW/	AT	us- 5,952,356	09-14-1999	Ikeda et al.	

[illegible]

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7 There will vary depending upon the needs of the individual case

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		Art Unit	
		Examiner Name	
Sheet 2	of 5	Attorney Docket Number	141-446

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		Number - Kind Code ² (if known)				
/KW/	AT	US- 5,955,106	09-21-1999	Moeckel et al.		
/KW/	AV	US- 6,011,049	01-04-2000	Whitcomb		
/KW/	AW	US- 6,031,004	02-29-2000	Timmins et al.		
/KW/	AX	US- 6,099,859	08-08-2000	Cheng et al.		
/KW/	AY	US- 6,153,632	11-28-2000	Rieveley		
/KW/	AZ	US- 6,191,162	02-20-2001	Byrd et al.		
/KW/	BA	US- 6,248,363	06-19-2001	Patel et al.		
/KW/	BB	US- 6,291,495	09-18-2001	Rieveley		
/KW/	BC	US- 6,296,874	10-02-2001	Cutie et al.		
/KW/	BD	US- 6,329,403	12-11-2001	Odaka et al.		
/KW/	BE	US- 6,383,471	05-07-2002	Chen et al.		
/KW/	BF	US- 6,403,121	06-11-2002	Adjei et al.		
/KW/	BG	US- 6,451,342	09-17-2002	Adjei et al.		
/KW/	BH	US- 6,475,521	11-05-2002	Timmins et al.		
/KW/	BI	US- 6,524,621	02-25-2003	Adjei et al.		
/KW/	BJ	US- 6,599,284	07-29-2003	Faour		
/KW/	BK	US- 2002/0071866	06-13-2002	Geerke		
/KW/	BL	US- 2003/0113371	06-19-2003	Dhawan et al.		
/KW/	BM	US- 2003/0118647	06-26-2003	Seth		
/KW/	BN	US- 2003/011864	06-26-2003	Gao et al.		

FOREIGN PATENT DOCUMENTS							
Examiner Initials ¹	Cite No. ¹	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³	-Number ⁴ - Kind Code ⁵ (if known)				
/KW/	CA	WO	96/09823	04-04-1996	Luo et al.		
/KW/	CB	WO	98/11879	03-26-1998	Shell et al.		
/KW/	CC	WO	98/55107	12-10-1998	Shell et al.		
/KW/	CD	WO	99/47128	09-23-1999	Timmins et al.		
/KW/	CE	WO	99/55320	11-04-1999	Nishii et al.		
/KW/	CF	WO	00/28989	05-25-2000	Lewis et al.		
/KW/	CG	WO	00/72827	12-07-2000	Straub et al.		
/KW/	CH	WO	01/35940	05-25-2001	Lewis et al.		
/KW/	CI	WO	01/35941	05-25-2001	Lilliot et al.		
/KW/	CJ	WO	01/82875	11-08-2001	Cutie et al.		

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Substitute for form 1449A/PTO

(use as many sheets as necessary)

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Complete if Known

Application Number	10/777,542
Filing Date	February 12, 2004
First Named Inventor	Unchalee Kositprapa
Art Unit	
Examiner Name	
Attorney Docket Number	141-446

[illegible]

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		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
/KW	CK	WO 02/28181	04-11-2002	Gidwani et al.		
/KW	CL	WO 03/004009	01-16-2003	Matharu et al.		
/KW	CM	WO 03/035029	05-01-2003	Louie-Helm et al.		
/KW	CN	WO 03/047529	06-12-2003	Seth et al.		
/KW	CO	EP 0 169 105	01-22-1986	Zentner et al.		
/KW	CP	EP 0 283 369	09-21-1988	Wiernsperger et al.		
/KW	CO	EP 0 381 181	08-08-1995	Wenzel et al.		
/KW	CR	EP 0 749 751	12-27-1996	Ikeda et al.		
/KW	CS	EP 0 753 298	11-21-2001	Tsujita et al.		
/KW	CT	EP 0 781 129	07-02-1997	Moeckel et al.		

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Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i> Sheet <u>4</u> of <u>5</u>		Complete if Known Application Number <u>10/777,542</u> Filing Date <u>February 12, 2004</u> First Named Inventor <u>Unchalee Kositprapa</u> Group Art Unit _____ Examiner Name _____ Attorney Docket Number <u>141-446</u>
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OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS		
Examiner Initials ¹	Cite No. ²	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published
/KW/	DA	P. Karttunen et al., International Journal of Clinical Pharmacology, Therapy and Toxicology, "The pharmacokinetics of metformin: a comparison of the properties of a rapid release and a sustained-release preparation" Vol. 21, No. 1 - 1983, pp. 31-36.
/KW/	DB	P.J. Pentikainen, International Journal of Clinical Pharmacology, Therapy and Toxicology, "Bioavailability of metformin. Comparison of solution, rapidly dissolving tablet, and three sustained-release products", Vol. 24, No. 4 - 1986, pp. 213-220.
/KW/	DC	Finnish Monograph of the Diformin®, Retard tablet, with English translation
/KW/	DD	O.J. Lucis, MD, Ph.D., MSC, Canada Medical Association J. Pharmacologic Update "The status of metformin in Canada" Vol. 128, January 1, 1983, pgs. 24-26.
/KW/	DE	G. Belcher and D.R. Matthews, Experiment and Clinical Endocrinology & Diabetes, "Safety and tolerability of pioglitazone" Suppl. 2 (2000) pgs. 267-273.
/KW/	DF	Daniel Einhorn, MD et al., Clinical Therapeutics "Pioglitazone Hydrochloride in Combination with Metformin in the Treatment of Type 2 Diabetes Mellitus: A Randomized, Placebo-Controlled Study", Vol. 22, No. 12, 2000 pgs. 1395-1413.
/KW/	DG	National Institute for Clinical Excellence Technology Appraisal Guidance - No. 21, "Guidance on the Use of Pioglitazone for Type 2 Diabetes Mellitus" March 2001, pgs. 1-13.
/KW/	DH	The Pharmaceutical Journal, Vol. 265, No. 7122, p. 710 November 11, 2000 Clinical (abstract only).

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		Filing Date	February 12, 2004
		First Named Inventor	Unchalee Kositprapa
		Group Art Unit	
		Examiner Name	
Sheet 5 of 5	Attorney Docket Number	141-446	

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
/KW/	DI	Product Labeling for Glucophage® XR (July 2002).	
/KW/	DJ	ADA Professional Section Member Supplement 0474 and 0503-506 (Poster) p. A110; A117	
/KW/	DK	Website www.findarticles.com, Clinician Reviews, "Insulin-Sensitizing Diabetes Agent" September 1999.	
/KW/	DL	ACTOS® product label, Physician's Desk Reference, 55th Edition, pp. 3171-3175	
/KW/	DM	Rote Liste No. 11081 the Medicament MEDIABET of Medice; GLUCOBAY of Bayer; and GLUCOTARD of Boehringer Mannheim, Chem.-Pharm. Fabrik Pütter GmbH & Co. KG, Kuhlweg 37-39 Iserlohn/Germany, Editio Cantor Verlag für Medizin und Naturwissenschaften GmbH, 1993.	
/KW/	DN	Abdallah et al., "Preparation and Evaluation of Metformin Hydrochloride Controlled-Release Tablets" STP Pharma 4(1) pp. 15-20, 1988.	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet

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Complete if Known

Application Number	10/777,542
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Filing Date	February 12, 2004
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First Named Inventor	Unchalee Kositprapa
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Art Unit	1615
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Examiner Name	Not yet assigned
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Attorney Docket Number	141-446
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U. S. PATENT DOCUMENTS

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		Country Code ³ Number ⁴ Kind Code ⁵ (if known)	MM-DD-YYYY			
/KW/	CU	WO99/47125	04-12-2005	Conley et al.		
/KW/	CV	EP 1 588 708 A1	10-26-2005	Takeda Pharm Co		

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